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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,108	10/08/2004	Ruediger Ridder	05033.0006.PCUS00	8587

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EXAMINER	
JOYCE, CATHERINE	
ART UNIT	**PAPER NUMBER**
1642	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,108	RIDDER ET AL.	
	Examiner	Art Unit	
	Catherine M. Joyce	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-26* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-26 are pending.

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

1. Claims 1-17, 22-24, as drawn to a method for discriminating $p16^{INK4a}$ overexpressing metaplasias from $p16^{INK4a}$ overexpressing neoplastic lesions in a biological sample in the course of cytological testing procedure comprising (a) determining the presence or absence of cells overexpressing of $p16^{NK4a}$ in the biological sample, (b) determining the presence or absence of cells expressing at least one high risk HPV gene-product in the biological sample, *wherein the gene product is a polypeptide*, and (c) assessing simultaneous presence of cells expressing high risk HPV gene-products with cells overexpressing $p16^{INK4a}$ or the presence of cells expressing $p16^{INK4a}$ alone, wherein the simultaneous presence of cells expressing high risk HPV gene products with cells overexpressing $p16^{INK4a}$ is indicative for neoplastic or preneoplastic lesions.

2. Claims 1-15,17-21, 22-24 as drawn to a method for discriminating $p16^{INK4a}$ overexpressing metaplasias from $p16^{INK4a}$ overexpressing neoplastic lesions in a biological sample in the course of cytological testing procedure comprising (a) determining the presence or absence of cells

overexpressing of $p16^{NK4a}$ in the biological sample, (b) determining the presence or absence of cells expressing at least one high risk HPV gene-product in the biological sample, *wherein the gene product is a polynucleotide*, and (c) assessing simultaneous presence of cells expressing high risk HPV gene-products with cells overexpressing $p16^{INK4a}$ or the presence of cells expressing $p16^{INK4a}$ alone, wherein the simultaneous presence of cells expressing high risk HPV gene products with cells overexpressing $p16^{INK4a}$ is indicative for neoplastic or preneoplastic lesions.

3. Claims 25 and 26, as drawn to a diagnostic or research kit comprising (a) probes for the detection of presence or absence of the overexpression of $p16^{INK4a}$ in biological samples and (b) one or more probes for the detection of the presence or absence of the expression of one or more HPV gene-products in biological samples.

3. The inventions are distinct, each from the other, because of the following reasons:

The inventions listed as Groups 1-3 do not relate to a single inventive concept because they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups 1-3 appears to be that they all relate to the use of detection of $p16^{INK4a}$ in combination with the detection of an HPV gene product in the detection of cervical neoplasia. However, Agoff et al (2003, Modern Pathology 16(7):665-73) specifically teaches both the use of $p16^{INK4a}$ and in combination with the detection of an HPV gene product in the detection of cervical neoplasia. Therefore the technical feature linking the inventions of Groups 1-3 does not constitute a special technical feature as it does not define a contribution over the prior art.

In view of the above, Group 1 is considered the main invention. After that, all

other products and methods have been broken out as separate groups (see 37 CAR 1.475(d).).

An international stage application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. When claims to different categories are present in the application, the claims will be considered to have unity of invention if the claims are drawn only to one of the following combinations of categories: (1) A product and a process specially adapted for the manufacture of said product; or (2) A product and a process of use of said product; or (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or (4) A process and an apparatus or means specifically designed for carrying out the said process; or (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specifically designed for carrying out the said process. If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application will be considered as the main invention in the claims, see PCT article 17(3) (a) and 1.476 (c), 37 C.F.R. 1.475(b) and (d). Group I will be the main invention. After that, all other products and methods will be broken out as separate groups (see 37 CFR 1.475(d).)

4. Further, the following elections of species are required.

If Groups 1 or 2 are elected, election of specific HPV gene product from the following list is required: E7, E2, E6, L1, L2.

If Groups 1 or 2 are elected, election of specific label from the following list is required: a radioisotope, a bioluminescent compound, a chemiluminescent compound, a fluorescent compound, a metal chelate, an ezyme.

If Groups 1 or 2 are election, election of probe from the following list is required: a polypeptide; a nucleic acid.

If Group 2 is elected election of a nucleotide detection method from the following list is required: in situ hybridization; a nucleic acid amplification reaction.

If a nucleic amplification reaction above is elected election of a specific reaction type from the following list is required: LCR or PCR.

If Groups 1 or 2 are elected, election of a specific HPV subtype from the following list is required: 16, 18, 31, 33, 35, 39, 39, 45, 51, 52, 56, 58.

5. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

6. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103 of the other invention.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

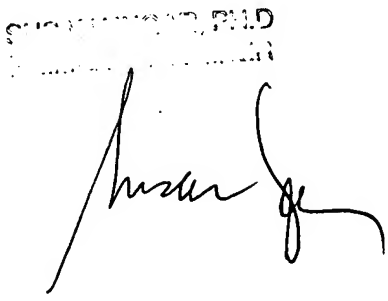
8. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

9. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine M. Joyce whose telephone number is 571-272-3321. The examiner can normally be reached on Monday thru Friday, 10:15 - 6:45.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shanon Foley, can be reached on 571-272-0898. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8700.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Catherine M. Joyce
Examiner
Art Unit 1642